K092214

510(k) Summary for the Bien-Air Dental SA Chiropro L system

DEC 15 2009

1. SPONSOR

Bien-Air Dental, SA
Langasse 60
CH - 2504 Bienne
Switzerland

Contact Person: Helena Lacalle-Baumann
Telephone: +41-32-344-64-64

Date Prepared: July 20, 2009

2. DEVICE NAME

Proprietary Name:	Chiropro L system
Common/Usual Name:	Controller
Classification Name:	Controller, foot, handpiece and cord (Product Code EBW) under 21CFR 872.4200, dental handpiece and accessories

3. PREDICATE DEVICES

- implantMED SI-915/923, W & H Dentalwerk, K052741
- TI-Max-SG20L, NSK Nakanishi Inc., K970953
- WS-75 E/KM (W & H Dentalwerk Buermoos GmbH, K011061)

4. INTENDED USE

The Chiropro L system is intended for use in dental surgery, endodontics, and implantology. The main unit is designed to operate a specific dental micromotor that drives dental handpieces fitted with appropriate tools to cut hard and soft tissues in the mouth and to screw dental implants.

5. DEVICE DESCRIPTION

The Chiropro L system consists of a software-based drive unit that controls the speed of a dental micromotor. The Chiropro L system offers three different functional modes with operating parameters specific to a particular application (Implantology,

Endodontics, and Dental Surgery).

The Chiropro L system is equipped with an integrated peristaltic pump for use with external irrigation tubing allowing irrigation of the working area. The device is operated via the command buttons on the tabletop console or through a foot control.

For implantology purposes, the Chiropro L system is intended to be used with a contra-angle handpiece with a 20:1 gearing ratio and a rotational speed between 5 rpm to 2000 rpm (designed to operate burs according to ISO1797-1, type 2). Two versions of the handpiece are available, with and without optical fibers conducting the light emitted by the motor to the surgical field.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The proposed Chiropro L system is identical in intended use, overall design, and function to the implantMED SI-915/923. Both the proposed and predicate devices are drive units consisting of a control unit with an integral irrigation pump and tubing, micromotor, and connecting cable. In addition, the handpieces supplied with the Chiropro L system are similar in overall design and functional characteristics to the predicate handpieces, the Ti-Max-SG20L and WS-75 E/KM.

Testing provided in this premarket notification includes electrical safety and electromagnetic compatibility testing. Test results demonstrate that the Chiropro L system can be used safely and effectively as a drive unit for dental handpieces intended for use in dental surgery, endodontics, and implantology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Bien-Air Dental, SA
C/O Ms. Cynthia J. Nolte
Senior Regulatory Consultant
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

DEC 15 2009

Re: K092214
Trade/Device Name: Chiropro L System
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EBW
Dated: December 8, 2009
Received: December 10, 2009

Dear Ms. Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, BS, MS, MBA
Director
Division of Anesthesiology, General Hospital,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Chiropro L system

Indications for Use:

The Chiropro L system is intended for use in dental surgery, endodontics, and implantology. The main unit is designed to be used with a specific dental micromotor that drives dental handpieces fitted with appropriate tools to cut hard and soft tissues in the mouth and to screw dental implants.

Prescription

Prescription Use __x__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

RSBepz DDS for Dr. K. Mulay (Acting)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092214